Micro tools

This invention concerns micro-surgical tools that can be delivered through or by a catheter or needle. These tools or micro-structures can be used to adapt, assemble, separate, fortify, dilate, close and hold biological structures inside the body during and after surgery. The tools may be stents, valves, clips, nets, knives, scissors, dilators, clamps, tweezers etc.

Introduction

The use of microstructures to assemble, fortify or dilate biological structures inside the body during and after surgery can help the surgeon in a number of ways. The operation of electrically actuated tools can help the surgeon to simultaneously position, operate manually, and observe. By positioning the tool by hand and separately operating it through external control (i.e. footswitch, voice control, other software-control) a much higher degree of precision is expected. In microsurgery, this is an especially desired advantage.

To be able to apply, beforehand or during an invasive procedure, a tool of a required size and geometry - designed for the purpose of cutting, drilling, holding, dilating, suturing, adapting or supporting - from tools that, for example, could be introduced through, placed inside or located at the end of a catheter or needle, is another desired function, requiring development of microactuators.

-The application of structures in or introduced through a catheter or needle is of particular interest at the application of tools, which are to be left at the site after insertion, and which have to execute their function for some limited time duration. The first example here is that of clips for surgery, sub-millimeter to millimeter structures, which would be used to hold two separated biological structures joined, for example during a healing period (Fig.1A - 1C).
-Another example is that of structures for controlling the flow through blood vessels. The simplest level is that of a clip used to prevent blood flow to a biological structure downstream in the blood flow. Such a clip, or series of clips, would be mounted and left to hold a firm grip

on the blood vessel and thus to prevent the flow of blood. In Figure 2 is shown a series of structures suitable for constricting blood vessels.

-The third example is at a somewhat more complex level with structures built in a geometry where they could be used inside or outside tube-like structures, as so called stents to dilate a stenotic area or to internally or externally fortify or join the structure(s) (Figure 5A and 5B). Stents are of particular interest since they are to be inserted inside the tube, then to be left there to expand a stenotic (examples: blood vessel, biliary duct) or to fortify a weak (examples: blood vessel with aneurysm, divided biliary duct) part of a tubular structure .

Arrays of fingers could be used to hold cylindrical objects, such as nerves and nerve fibers, or blood vessels. With the help of microactuators holding the structures (Fig. 3A - 3B), adjacent microstructures operating as neural sensing or activating electrodes, will enable recording signals from or activating nerves. This could be used as a synthetic neural connector, bridging a severed nerve or nerve fiber.

Elements with some temporary mechanical function could be inserted in membranes (Fig.4A - 4C). Insertion devices of this kind could be used for mounting a hole through a membrane such as commonly used in ear surgery for pressure equilibration. Making these as microdevices will much decrease the effort to place and remove the inserted devices and to keep them in place during the desired time period.

Clips, stents, finger arrays and insertion devices, once applied, could be resorbable or permanent. They could express various degrees of stimulation of cell growth on its surfaces, various degrees of anti-thrombotic activity as well as different antibiotic activities. They can also be carriers of various biochemical or biological components.

The necessary elements to accomplish these functions are the electrochemically activated micromuscles, built by micromachining thin metal and polymer layers (Elisabeth Smela, Olle Inganäs and Ingemar Lundström: "Controlled Folding of Micron-size Structures", Science 268 (1995) pp.1735-1738) or only polymer layers. These actuators can be produced in sizes from micrometers to centimeters, and operate well in biological fluids such as blood plasma, blood, buffer and urine. They are therefore suitable tools for micro invasive surgery inside the body.

The versatility of construction and the speed of response, as well as the force of these actuators render them as one of the best types of microactuators inside the body. An international patent covers one route of fabrication of such devices (A Elisabeth Smela, Olle Inganäs and Ingemar Lundström: "Methods for the fabrication of micromachined structures and micromachined structures manufactured using such methods ", Swedish patent application number SE 9500849-6, March 10, 1995 in succession also a PCT and international patent).

Prior art

The combination of microactuators and catheters are not well documented in the literature. A patent search reveals a few examples but none that describes the use of microactuators as tools housed inside a catheter; several examples of microactuators use to position a catheter are to be found in the following patents

US5771902	Micromachined actuators/sensors for intratubular positioning/steering
US5819749	Microvalve
WO9837816A1	Microfabricated therapeutic actuators
WO9739688A2	Method and apparatus for delivery of an appliance in a vessel
WO9739674A1	Spring based multi-purpose medical instrument
US5855565	Cardiovascular mechanically expanding catheter

Several mechanisms are suggested for the microactuators in these applications, found among shape memory alloys (including polymeric materials) and piezoelectric materials. The use of conjugated polymers in micromuscles is not documented for catheter tools. Our novelty and innovation therefore resides in the use of microactuators based on conjugated polymers being electrically operated and mounted in or on a catheter or needle, to be positioned with the help of the catheter, and then activating the microactuator structures carried on the needle. The microfabrication of such microactuators renders possible a number of geometries from 10 µm and larger, difficult to produce by mechanical production techniques. They may be produced by use of the method presented in patent A above and then mounted in or on the needle or catheter, or they might be produced by novel manufacturing methods. With the help of this invention, completely novel microsurgery tools are available.

The production of individually actuated tool arrays render little difficulty beyond that of producing the individual tool; we have to see that electrical contacts are supplied to actuate each microactuator separately. This can be done by wiring the single microactuator. to be used as the working electrode; the catheter is then used as the counterelectrode, and will be able to supply all the charge that we ever need to actuate all those microactuators. As wires may easily be produced in width down to 10 µm with photolithography or with soft lithography, we will be able to put at least 50 microactuators along the tool array located in/on a needle of 1 mm width, with the simple philosophy of putting down parallel conductor wires. Should we need more, more elaborate addressing schemes might be needed.

Should a necessity for three electrode systems be found in any of the applications, microfabricated reference electrodes or macrosize reference electrodes carried on the catheter housing offers a solution for this problem.

Should the tool arrays be collectively addressed, and the tool array is designed to set free the outermost clip on actuation of all the clips, we will need a mechanism of confining the movements of all but the outermost clip. This is done by assembling the clip array into a cylindrical housing, preferably the catheter, prior to insertion in the body. The cylindrical housing is now confining the motion of microactuators, which search in vain to expand the strong metal casing on operation. When the outermost clip C1 is actuated, the clip is opened; likewise is the next-to-the outermost clip C2 partially free to move as it is protruding outside the cylindrical housing. Therefore the partial opening of C2 sets C1 free, as well as opens it up for subsequent spontaneous closing on the site to be clipped.

Figure captions

Figure 1A - 1C shows clips and clip arrays, where the clips are mounted in sequence, and area confined by a cylindrical housing, and where the activation of the outer most clip C1, opening up the clip to join the open structure W1, and then being set free by the simultaneous operation of C2, so as to be left at the structure W1, holding the structures together.

Figure 2 shows tubular tweezers, tweezers and knifes, based on microactuators. The indicated movement is driven by microactuators properly mounted and designed.

Figure 3A - 3B shows a neural connector, where a number of small fingers coil around a cylindrical nerve to make a tight hold the nerve. Two separate nerves are here joined with the help of a common neural connector, which would be desired for accomplishing regrowth of the nerves. In addition, small electrodes can be fashioned along with the microfingers, and be used to sense or excite nerve signals.

Figure 4A - 4C. An insertion devise, for making a temporally permanent hole through a membrane. The devise is housed in a catheter/cannula/needle and is inserted through the membrane so as to make the devise form a hole through the membrane.

Figure 5A - 5B show a stent device.